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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,533	RAI ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-28* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendments filed February 23, 2009 and October 10, 2008 are acknowledged. The examiner acknowledges the amendments to the specification. Claims 1-22 are cancelled. Claim 28 is withdrawn. Claims 23, 24 and 27 are amended. Claims 23-27 are under consideration I this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of the specification;

b) The objection of claims 23 and 26; and

c) The rejection of claims 23-27 under 35 U.S.C. 112, second paragraph

Response to Arguments

3. Applicant's arguments filed October 10, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 24-26 under 35 U.S.C. 102(b) as being anticipated by Lim et al., (J. Clinical Microbio. 1987. Vol. 25(7): 1165-1168) is maintained for reasons already of record.

Applicants argue that antibody of Lim is antibodies specific to *Salmonella typhi* and *Salmonella panama*, whereas the instantly claimed reagent has an antibody specific to *Salmonella typhi*. Therefore Lim et al., do not anticipate the claims.

However it is the position of the Office that the antibody of Lim et al., meet the instantly recited limitations because, as Applicants agree, the antibody is specific to *Salmonella typhi*. The fact that the antibody of Lim et a., is specific to an additional *Salmonella* species, do not teach away of prevent the antibody from being specific to *Salmonella typhi*. Furthermore, the additional binding abilities do not prevent the 0-9 antibody from meeting the instantly claimed limitations. Therefore as long as the 0-9 antibody of Lim et al., is specific to *Salmonella typhi*, it meets the limitations of the claims.

Applicants assert that the latex particles are not carboxylated latex particles, in contrast to the instantly claimed invention. However, Lim et al., teach latex particles coated with a monoclonal antibody specific for *Salmonella typhi* (abstract). Lim et al., teach a 1% suspension of latex particles (page 1165, col.2). These carboxylated latex beads are commercial available from Sigma (page 1165, col.2). Lim et al., teach the need to sensitize the particles with the same instantly claimed reagents necessary to treat and sensitize the carboxylated latex particles. Furthermore, the particles of Lim et al., are colored and the colored latex particles commercially available from Sigma were

carboxylated. Therefore Applicants mere arguments without any evidence to the contrary are not persuasive, therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of claims 23-27 under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al., (Electrophoresis. 2001. Vol. 22:2384-2390) and Salzman et al (WO 01/40280 published June 1, 2001) in view of Sukosol et al., (Asian Pacific J. of Allergy and Immuno. 1994. Vol. 12. pages 21-25) is maintained for reasons already of record.

Applicants urge that claim 23 recites that recited invention teaches that the washing step is performed with 20 mM MES buffer of pH 5.5 and that the coating is stopped with 1M glycine (pH 11.0) and that the Office Action does not explain why one of ordinary skill in the art would use MES buffer and 1M glycine instead of Tris-BSA and Tris-HCL, therefore *a prima facie* case of obviousness has not been established.

However it is noted that Nilsson et al., teach using affinity purified antibodies, carboxylated latex particles, 2-(N-Morpholino)ethane sulfonic acid (MES), ethyl-3(3-dimethylaminopropyl)-carbodiimide (EDC), Bovine serum albumin (BSA), TWEEN 20, Tris, sodium hydroxide, and other reagents. Nilsson et al., teach the carboxylated latex

particles were washed in MES buffer, pH 5.5 and resuspended. EDC was added to the particles. Nilsson et al., antibody solution containing BSA was added to the activated particles. Therefore the references teach using the same instantly disclosed reagents.

Furthermore, it would have been *prima facie* obvious at the time of applicants' invention to apply an antibody specific to *Salmonella typhi* as taught by Sukosol et al., and the preparation of the antibody as taught by Salzman et al., to the method for the preparation of latex particles as taught by Nilsson et al., in order to provide improve the detectability. Also, it would have been prima facie obvious to combine the invention of Salzman, Sukosol and Nilsson et al., to advantageously achieve a general method applicable to most proteins that creates a system for highly selective and sensitive protein detection. Thus, contrary to Applicants assertion, a prima face case of obviousness has been established.

Applicants argue that the specificity of the antibody will be low, in contrast, the recited invention is directed to using a portion/fragment of flagellin gene sequence specific to *S. typhi*, and is prepared with polyclonal monospecific antibodies. However Sukosol et al., teach the production of recombinant fusion protein of flagellin protein from *Salmonella typhi* Sukosol et al., teach the construction and screened for the recombinant clones expressing specific *S. typhi* antigens and that the antibodies do not cross react with related proteins. Therefore contrary to applicants' statements about antibodies with low specificity, the references teach antibodies with high specificity. One of ordinary skill in the art would have a reasonable expectation of success by exchanging the flagellin *Salmonella* typhi antibody with other *Salmonella* flagellin

antibodies because are they are known to be recombinantly prepared and capable of being coated onto latex particles in order to provide specific binding.

Applicants assert that Sukosol uses a GST as a tag, while in contrast, the recited invention is practice using a 6X histine tag containing vector; therefore since the references do not teach using a 6X histine tag, the invention is patentable over the cited prior art. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., using a 6X histine tag are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore the fact that they are differences whose limitations are not claimed is not found persuasive and the rejection is maintained.

New Grounds of Rejection Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an a process for preparing an agglutination reagent for detecting typhoid comprising preparing a polyclonal-monospecific antibody specific to *Salmonella typhi* and coating a latex particle with the polyclonal-monospecific antibody. Applicant did not point to support in the specification for preparing the polyclonal-monospecific antibody specific to *Salmonella typhi* as recited by the amended claims. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the polyclonal-monospecific antibody specific to *Salmonella typhi* and coating a latex particle with the polyclonal-monospecific antibody. Thus, there appears to be no teaching of a process for preparing an agglutination reagent for detecting typhoid comprising preparing a polyclonal-monospecific antibody specific to *Salmonella typhi* and coating a latex particle with the polyclonal-monospecific antibody. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity an a process for preparing an agglutination reagent for detecting typhoid comprising preparing a polyclonal-monospecific antibody specific to Salmonella typhi and coating a latex particle with the polyclonal-monospecific antibody as recited by the amendments. Therefore, the claims incorporate new matter and are accordingly rejected.

Conclusion

7. No claims allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645